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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/785,348	02/24/2004	Susan Shelso	1001.1725101	8750

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EXAMINER	
SCHELL, LAURA C	

ART UNIT	PAPER NUMBER
3767	

MAIL DATE	DELIVERY MODE
12/23/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/785,348	SHELSO ET AL.	
	Examiner	Art Unit	
	LAURA C. SCHELL	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 September 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9,12,16,17 and 19-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9,12,16,17 and 19-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 9, 12, 16, 17, & 19-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Griffin et al. (US 2003/0125751) in view of Muni et al. (US Patent No. 5,316,706). Griffin discloses the device substantially as claimed including a medical device comprising: a guidewire (Fig. 6a discloses an embodiment with a guidewire (21)) having a first diameter (diameter of the guidewire 21) and a distal stop having a second diameter greater than the first diameter (distal stop is 29 which has a different diameter; also see paragraph [0187]); an elongate tubular member (Figs. 49 and 50, 210) having a proximal end (near 2) and a distal end (near 31) with a guide wire receiving lumen (7) extending therethrough, a distal portion of the guidewire lumen having an inner diameter of substantially the same magnitude as the first diameter (portion 13 clearly has a lumen

within it that snugly encompasses the diameter of the guidewire); and a tip (the tip beginning at where the portion 13 ends and the tip. extends distally until the very distal-most part of 202) disposed at the distal end of the elongate tubular member and having a distal end (near 202), a proximal end (near 5) and a lumen therethrough (lumen which 21 passes through), the tip having an elastic portion (portion 31 is an elastic portion) and a radially inextensible distal portion distal of the elastic portion (202 is distal of elastic portion 31 and is radially in extensible; Figs. 46 and 47 as well as paragraph [0302] and Figs. 37-39 disclose that the distal end of the catheter is made of flexible material, designed to deform upon compression and contact. Furthermore, paragraph [0303] discloses that the radially inextensible ring acts as a stop when contacting the filter. Also see paragraphs [0266], [0267] and [0303] which disclose that portion 31 is a deformable polymeric material but portion 202 is a harder material which acts as a stop when it abuts the stop on the guidewire and prevents the distal end of the catheter from deforming around the stop of the guidewire); wherein the radially inextensible distal portion is a distal most extremity (Figs. 46, 47, 49 and 50 disclose that the very distal tip of 202 is the distal-most extremity of the catheter). Griffin, however, does not disclose that the tip comprises an amorphous polymer or that the radially inextensible distal portion comprises a locally crystalline section thereof.

Muni, however, discloses a catheter and method of making a catheter, in which softer sections are made from amorphous polymers and the hardened sections are made from crystalline sections (col. 3, lines 33-39 disclose the relationship between crystallinity and hardness, while col. 3, line 60 through col. 4, line 29 disclose that the

crystalline and amorphous sections can be altered so that the catheter can have any pattern of hardness and softness. Specifically, col. 4, lines 18-22 disclose that catheter does not have to be limited to the stiff portion being the body portion and the soft portion being the tip, and also discloses that the crystallinity may be "varied in any of a plurality of zones throughout the length" thus indicating that many different portions can be soft or crystallized, depending on what is preferred. Therefore it would have been obvious to one of ordinary skill in the art, due to this teaching to have made a portion distal of the amorphous portion of the tip, crystalline). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Griffin with the method and pattern of hardening catheter sections by altering crystallinity, as taught by Muni, in order to provide another source of a hardened tip for the catheter, especially since Muni discloses that the regions of crystalline and the softer amorphous polymer regions can be varied.

In reference to claim 12, Griffin discloses that the radially inextensible distal portion comprises a ring having a lumen therethrough (Figs. 49 and 50 disclose that 202 has a lumen through it).

In reference to claims 16 and 17, as defined by MPEP 2113, product by process claims are not limited to the recited steps, only the structure implied by the steps. Therefore the distal portion is anticipated by Griffin.

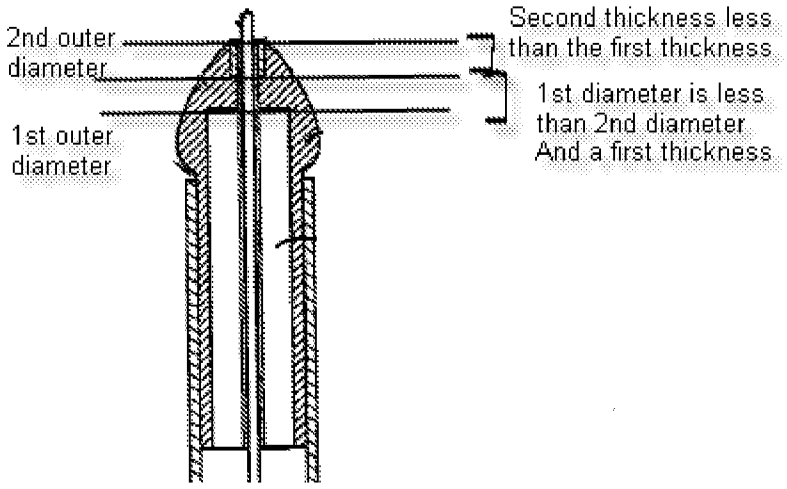
In reference to claim 19, Griffin discloses that the radially inextensible distal portion comprises a non-compliant plastic band (paragraph [0303]).

In reference to claim 20, Griffin discloses that the tip further comprises a flexible portion proximate the radially inextensible distal portion (portion 31 is more flexible than portion 202; see paragraph [0303]).

In reference to claim 21, Griffin discloses that the radially inextensible distal portion is a distal most extremity (202 is the distal most extremity) and wherein the flexible portion is proximal of the radially inextensible distal portion (portion 31 is proximal to 202), wherein the flexible portion tapers from a first outer diameter at a first location along the tip to a second outer diameter less than the first outer diameter at a second location along the tip distal of the first location (see Figs. 49 and 50 and the marked-up version of Fig. 49 at the end of the office action).

In reference to claim 22, Griffin discloses that at the first location along the tip, the tip has a first thickness and a first inner diameter, and wherein at the second location along the tip distal of the first location, the tip has a second thickness less than the first thickness and a second inner diameter greater than the first inner diameter (see Fig. 49 and the marked up version of Fig. 49 at the end of the office action).

In reference to claim 23, Griffin discloses that the flexible portion comprises an inner surface concave in a first plane normal to a longitudinal axis and a second plane normal to the first plane (Fig. 49).



Response to Arguments

Applicant's arguments with respect to claims 9, 12, 16, 17, 19-23 have been considered but are moot in view of the new ground(s) of rejection.

With respect to Applicant's arguments that Muni does not teach crystallizing the distal end of the catheter, the examiner again points to col. 4, lines 18-22 in the Muni reference which discloses that the catheter does not have to be limited to the stiff portion being the body portion and the soft portion being the tip. It is the examiner's position that it would have been obvious, with this teaching in the reference, to crystallize a distal portion of the catheter in cases where the distal tip of the catheter needs to be harder than the proximal portion, as is taught by Griffin. It is the examiner's suggestion that more structural language concerning the tip be added in an amendment.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA C. SCHELL whose telephone number is (571)272-7881. The examiner can normally be reached on Monday-Friday 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Laura C Schell/
Examiner, Art Unit 3767

/Patricia Bianco/
Supervisory Patent Examiner, Art Unit 3772